Remarks / Arguments

This amendment is provided concurrently with a Notice of Appeal to simplify the issues for appeal. Claims 1 and 17 are amended and claim 23 is canceled.

I.
Support for Amendments

Amendments to the claims are supported throughout the application including the specification as filed.

Claims 1 and 17 are amended to recite that the signal peptide is a secretion signal peptide.

Exemplary support for the amendment may be found at page 7, lines 11-21, which provide,

> "In a further preferred embodiment, the nucleic acid construct used for the transformation encodes not only the desired proteinaceous substance, but also a transit peptide for secreting the substance from the host cell into the culture medium...The use of signal peptides for the endoplasmic reticulum or cellular transport is especially preferred."

Further support may be found at pages 14-16, which provides construction of an expression cassette encoding the protein VEGF and a human ER transit peptide used to direct secretion of the resulting heterologous proteinaceous substance into the medium thereby functioning as a secretion signal peptide; pages 17-18, which disclose transformation and growth of moss with the expression cassette; and page 27, which demonstrates successful secretion of VEGF in medium from moss transformed with the expression cassette.

II.
Response to Rejections Under 35 U.S.C. § 112, First Paragraph

The basic policy requirements specified under 35 U.S.C. § 112, first paragraph centers on the exchange of valuable consideration between the patent applicants and the public; that is, the patent application must disclose sufficient information to describe the invention and to enable

those skilled in the art to make and use the invention. If these disclosure requirements are satisfied the public receives valuable information in exchange for the patent grant conferred on the invention. If the requirements are not met, the public receives inferior information that might not be beneficial. Thus, the provision requires the specification include both a written description of the invention as well as an enabling description (i.e. how to make and use the invention).

A. **Claim 23 complies with the written description requirement; however, to simplify issues for appeal, claim 23 is canceled.**

Claim 23 is rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. Specifically, the examiner argues that neither the specification nor the originally filed claims appear to provide support for the expression of F(ab) or F(ab')2.

The written description requirement places in possession of the public what the applicant considers to be the invention for which a patent is being sought. The CCPA in In re Wertheim, 191 USPQ 90, 96 (C.C.P.A. 1976), summarized the written description requirement as,

> "It is not necessary that the application describe the claim limitations exactly,...but only so clearly that persons of ordinary skill in the art will recognize from the disclosure that applicant's invented processes include those limitations."

Satisfaction of the written description requirement does not require *in haec verba* antecedence in the originally filed application. Staehelin v. Secher, 24 USPQ2d 1513, 1519 (B.P.A.I. 1992). All that is required is that the application reasonably convey the claimed subject matter. Ex parte Parks, 30 USPQ2d 1234 (B.P.A.I. 1994). One consideration is whether the technology claimed was developed prior to or subsequent to the filing of the patent application. *See* Chiron Corp. v. Genentech, Inc. 70 uSPQ 689, 692-3 (Fed. Cir. 2004) (written description requirement was not met when the application claimed technology that was developed subsequent to the filing of the patent application).

Turning to the present application, the inclusion of functional antibody fragments as proteinaceous substances is clearly demonstrated in the specification at page 6, lines 5-19, which

states,

> "The term 'biologically active' as used in the present description means that the target substances provided with this attribute have the functional properties desired or required for the respective purpose. If, for example, it is desired to produce antibodies, the protein produced, or a functional fragment thereof, is biologically active when it is capable of establishing the expected specific binding with the antigen." (emphasis added)

It has long been known to those skilled in the art that an antibody includes both Fab and Fc regions, which are routinely chemically separated from one another to form functional antibody fragments. It is also well known that the Fab region is also referred to as the **f**ragment, **a**ntigen **b**inding region. Thus, the Fab region is well known to provide functionality since it binds antigen. The term F(ab')2 has also long been known to refer to two Fab or two fragment antigen binding regions. For completeness both Fab and F(ab')2 fragments are known to lack the Fc region. As such, the inclusion of an antibody or a functional fragment thereof within the specification reasonably conveys to one skilled in the art that the invention includes both F(ab) and F(ab')2 antibody fragments.

However, to simplify the issues for appeal, applicants cancel claim 23.

Accordingly, applicants respectfully request the rejection be withdrawn.

B. Claims 1-3, 17 and 22-24 are enabled under 35 U.S.C. § 112, first paragraph, prior to amendment; however, claims 1 and 17 are amended to simplify issues for appeal

Claims 1-3, 17 and 22-24 stand rejected under 35 U.S.C. §112, first paragraph as lacking enablement. Specifically the examiner argues that while the specification is enabling for isolating a heterologous protein from culture medium in which transformed *Physcomitrella patens* protonema were grown, wherein the protenema were transformed with a construct encoding a secretion transit peptide operably linked to the heterologous protein, it does not reasonably provide enablement for isolating a heterologous protein from culture medium in which transformed *Physcomitrella patens* protonema were grown, wherein the protonema were transformed with a construct encoding other kinds of transit peptides operably linked to the

heterologous protein. The Examiner noted that transit peptides that direct the protein to the mitochondria or chloroplast would not function in the claimed method, as use of these transit peptides would not result in the secretion of the heterologous protein.

The specification need not describe or enable the invention to a layperson. Rather. It need only describe the invention to one of ordinary skill in the art. Gen. Elec. Co. v. Brenner, 159 USPQ 335, 337 (D.C. Cir. 1968). As explained in Ajinomoto Co., Inc. v. Archer-Daniels-Midland Co., 56 USPQ 2d 1332, 1336 (Fed. Cir. 200) *cert. denied* 532 U.S. 1019 (2001),

> "Requiring inclusion in the patent of known scientific/technological information would add an imprecise and open-ended criterion to the content of patent specifications, could greatly enlarge the content of patent specifications and unnecessarily increase the cost of preparing and prosecuting patent applications, and could tend to obfuscate rather than highlight the contribution to which the patent is directed. A patent is not a scientific treatise, but a document that presumes a readership skilled in the field of the invention."

Claims 1 and 17, from which claims 2, 3, 22 and 24 depend are amended to recite that the signal peptide is a secretion signal peptide. Claim 23 is canceled. As acknowledged by the examiner in the Office Action, the specification does enable the inclusion of a secretion signal peptide. For example, page 27 demonstrates successfully assaying for the presence of VEGF in the culture medium, which was secreted from moss transformed with a construct encoding a secretion signal peptide, namely the human ER transit peptide, operably connected to the VEGF protein. Pages 14-16 demonstrate production of the construct itself and pages 17-18 demonstrate transformation and growth of moss with the construct.

Further page 7, lines 11-21, provides exemplary secretion signal peptides,

> "In a further preferred embodiment, the nucleic acid construct used for the transformation encodes not only the desired proteinaceous substance, but also a transit peptide for secreting the substance from the host cell into the culture medium...The use of signal peptides for the endoplasmic reticulum or cellular transport is especially preferred."

With respect to a proposed peptide that directs protein to the mitochondria or chloroplast, the peptide would not be a secretion signal peptide since secretion from the organism does not occur.

Accordingly, applicants respectfully request the rejections be withdrawn. Applicants provide notice of appeal.

III.

Response to Rejections Under 35 U.S.C. § 103(a)

A. Claims 1-3, 17 and 24 are not obvious over Reutter et al. in view of Raskin et al. and provide notice of appeal

For completeness, claims 1-3 and 17 and 24 stand rejected under 35 U.S.C. § 103(a) as being obvious over Reutter et al. (1996, Plant Tiss. Cult. Biotechnol. 1:142-147) in view of Raskin et al (US 6,096,546).

The above combination of references has been addressed in the response to Office Action dated October 13, 2006 (Amendment D), after which the substance of the response resulted in the withdrawal of rejections in the Office Action dated 1/18/2007.

Applicants provide notice of appeal.

B. Claims 22-23 are not obvious over Reutter et al. in view of Raskin et al. and further in view of Hein et al. and provide notice of appeal

Claims 22-23 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Reutter et al. in view of Rakin et al. as applied to claims 1-3, 17 and 24 and further in view of Hein et al. (US 5,959,177.

Claim 23 is canceled and claim 22 depends from claim 1. Applicants provide notice of appeal.

Conclusion

In view of the amendments and arguments set forth above, applicants respectfully submit the claims are in an improved condition for allowance.

Respectfully submitted,

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Date

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